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| APPLICATION NO. | , 1 | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|-------------------------------------------|------------|-------------|----------------------|-------------------------|-----------------|
| 10/657,577 | 09/08/2003 | | Michael B. Jaffe | 2077.1-3868.2US | 9869 |
| 24247 | 7590 | 11/29/2004 | | EXAMINER | |
| TRASK BRITT | | | | NASSER, ROBERT L | |
| P.O. BOX 2550 SALT LAKE CITY, UT 84110 | | UT 84110 | • | ART UNIT | PAPER NUMBER |
| • | | | | 3736 | |
| | | | | DATE MAILED: 11/29/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--|--|--|--|
| | 10/657,577 | JAFFE ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Robert L. Nasser | 3736 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period was - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | within the statutory minimum of thirty (30) days a reply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | _• | | | | | |
| 2a) This action is FINAL . 2b) ⊠ This | action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under E | x parte Quayle, 1935 C.D. 11, 45 | 33 O.G. 213. | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-10 is/are pending in the application. 4a) Of the above claim(s) 1-9 is/are withdrawn for the striction of the above claim(s) 1-9 is/are withdrawn for the striction and/or claim(s) 10 is/are rejected. 6) Claim(s) 10 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or | | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Examiner 11). | epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj | e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d). | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list of | s have been received. s have been received in Application ity documents have been received (PCT Rule 17.2(a)). | on No Id in this National Stage | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/8/03 and 9/24/03. | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other: | • | | | | |

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to an apparatus for introducing deadspace into a breathing circuit, classified in class 128 subclass 204.23.

- II. Claims 4-9 drawn to a method for estimating the partial pressure o carbon dioxide in alveolar blood, classified in class 600, subclass 532.
- III. Claim 10, drawn to a method for estimating the cardiac output, classified in class 600, subclass 532.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II and I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the apparatus could be used in a different method, such as in a method of ventilating a patient.

Inventions II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination (claim 4) recites many more details of the step of determining PAC02 than the combination. The subcombination has separate utility such as in making respiratory measurements.

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During a telephone conversation with Mr. Brick Power on September 23, 2004 a provisional election was made with traverse to prosecute the invention of Group III, claim 10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 10 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6648831 in view of Rayburn 6251082. Claim 8 of the patent recites all of the details of current

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claim 10, except for the fact that the alveolar carbon dioxide is determined based on the end tidal carbon dioxide. In column 2, lines 15-34, Rayburn teaches that it is well known to estimate alveolar carbon dioxide from an end tidal carbon dioxide measurement.

Hence, it would have been obvious to modify the previous invention to use this method of measuring alveolar carbon dioxide, as it is merely the use of a well known expedient in the art.

The examiner notes that the current application is ultimately a CIP of 08/770138, filed 12/19/1996. The examiner further notes that claim 10 finds support in the earlier patent and therefore is entitled to priority back to that date.

Claim 10 would be allowable if the double patenting rejection were overcome.

Claim 10 defines over the art of record in that none of the art determines carbon dioxide content from a measurement of the partial pressure of alveolar carbon dioxide and then calculates cardiac output from the change in end tidal carbon dioxide from before rebreathing to during rebreathing divided by the change in carbon dioxide content over the same interval, as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (571) 272-4731. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser Primary Examiner Art Unit 3736

Robert & Masson ?

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RLN November 19, 2004

> ROBERT L. NASSER PRIMARY EXAMINER